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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,917	07/09/2001	Henrik S. Olsen	1488.0440003	5233
22195	7590	12/23/2003	EXAMINER	
HUMAN GENOME SCIENCES INC			ROBINSON, HOPE A	
9410 KEY WEST AVENUE			ART UNIT	PAPER NUMBER
ROCKVILLE, MD 20850			1653	

DATE MAILED: 12/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/899,917	OLSEN ET AL.	
	Examiner	Art Unit	
	Hope A. Robinson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-116 is/are pending in the application.
- 4a) Of the above claim(s) 29,37,48,54,60,75,82,91,100,108 and 115 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 17-28,30-36,38-47,49-53,55-59,61-74,76-81,83-90,92-99,101-107,109-114 and 116 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's response to the Office Action mailed July 2, 2003 on October 6, 2003 is acknowledged.

Claim Disposition

2. Claims 1-16 have been canceled. Claims 17, 31, 39, 50, 56, 84, 93, 102 and 110 have been amended. Claims 17-116 are pending. Claims 17-28, 30-36, 38-47, 49-53, 55-59, 61-74, 76-81, 83-90, 92-99, 101-107, 109-114 and 116 are under examination.

3. The following grounds of rejection are or remain applicable :

4. The amendment filed October 6, 2003 is objected to under 35 U.S.C. 132 because the amendment introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the independent claims for example, claim 17 recite "wherein said protein stimulates the proliferation of myeloid cells" and there is no support for this in the instant specification. The response on page 15 points to the following pages of the instant specification for support but none was found. It is stated that "support is found in the specification *inter alia* at page 1, lines 10-12; page 5, lines 15-19; page 22, lines 13-17; page 26, lines 14-27; and page 28, line 23 through page 30, line 5. The specification discloses on page 1, lines 1012 that methods are provided (diagnostic methods) for detecting myeloid cells expressing

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the HOIPSI gene and therapeutic methods for treating cell-proliferative diseases, which does not equate to a product that stimulates the proliferation of myeloid cells. Therefore, there is no support in the instant specification for the function ascribed to the claimed protein.

Applicant is required to cancel the new matter in the reply to this office action.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 17-28, 30-36, 38-47, 49-53, 55-59, 61-74, 76-81, 83-90, 92-99, 101-107, 109-114 and 116 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are directed to an isolated protein comprising an amino acid sequence at least 90% identical to amino acid residues 1 to 142 of SEQ ID NO: 2 and the claims have no limitations to the function of the protein. Therefore, these claims are drawn to a large variable genus of polypeptides with unknown activity or inactive variants. In addition, the unspecified variants have not been adequately described in the instant specification as no special features or characteristics for the variants are provided. Therefore, the specification fails to describe representative species by identifying characteristics or structural properties other than having sequence similarity to SEQ ID NO: 2. Given this lack of description of the representative

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species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize that applicants were in possession of the invention as claimed.

The specification provides no measurable end point to allow one of skill in the art to be able to determine if a polypeptide that is in possession of another, and having at least 90% identity to SEQ ID NO:2, for example, falls within the description of the polypeptides as claimed. The specification does not describe polynucleotides encoding polypeptides having at least 90% identity to SEQ ID NO: 2 and do not have the asserted function, for example. The claims must recite a specific, measurable activity such that one can recognize a polypeptide as that claimed, or a fragment thereof. In order to make an accurate assessment of the modifications encompassed by these claims and to determine the function of the encoded protein fragment would require undue experimentation. Thus, functional language needs to be in the claim to provide a measurable end point.

In addition, the claims recite added material, which is not supported by the original disclosure. The independent claims for example, claim 17 recite "wherein said protein stimulates the proliferation of myeloid cells" and there is no support for this in the instant specification. Applicant points to several pages of the instant specification indicating that "support is found in the specification *inter alia* at page 1, lines 10-12; page 5, lines 15-19; page 22, lines 13-17; page 26, lines 14-27; and page 28, line 23 through page 30, line 5", but none was found. The specification discloses on page 1, lines 10-12 that methods are provided (diagnostic methods) for detecting myeloid cells expressing the HOIPS I gene and therapeutic methods for treating cell-proliferative diseases, which does not equate to a product that stimulates the proliferation of

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myeloid cells. Therefore, there is no support in the instant specification for the function ascribed to the claimed protein, thus the specification lacks adequate written description.

In view of the foregoing, at the time the application was filed, would not have taught one skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.

6. Applicant's response filed October 6, 2003 has been considered. It is noted that applicant provided the missing deposit information thus the rejection of record under 35 U.S.C. 112, first paragraph, written description has been amended, however, remains as the amendment introduced new matter. The amendment introduced new matter therefore the rejection has been tailored to include a new matter rejection and to maintain the rejection of the claims that recite percent homology without functional language. Applicant's response indicated that to expedite prosecution the claims were being amended to recite functional language, however, the language recited has no support in the instant specification. Amendments to the claims to remove the new matter and recite function will obviate this ground of rejection.

Conclusion

7. Applicant's amendment necessitated the new/modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


8. No claims are presently allowable.


Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 6:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703) 308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).


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Hope A. Robinson, MS 

Patent Examiner